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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Nicholas Mark Turner Adams

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EXAMINER

JOYNER, KEVIN

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,192	Applicant(s) ADAMS ET AL.	
	Examiner KEVIN C. JOYNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-78 is/are pending in the application.
- 4a) Of the above claim(s) 61,62 and 73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-60, 63-72 and 74-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/21/08, 6/3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 21, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 51-55, 57-59, 63, 65, 66, 69-72 and 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watling (WO 00/74734) in view of O'Neill et al (U.S. Patent No. 6,630,105).

Watling discloses a method of decontaminating an enclosed space, the method comprising the steps of:

Creating a recirculating heated airstream: (i) continuously drawing air from an atmosphere within the enclosed space to form an air stream, (ii) heating the airstream,

and (iii) emitting the heated airstream back into the atmosphere within the enclosed space (page 2, lines 4-15; pages 5 and 6, lines 5-37 & 1-37); and

Progressively introducing hydrogen peroxide/water vapour into the recirculating heated airstream until the atmosphere within the enclosed space reaches a dew point that causes the hydrogen peroxide/water vapour within the atmosphere to condense onto a surface bounding or within the enclosed space so as to decontaminate the surfaces (page 2, lines 5-30), the hydrogen peroxide/water vapour being produced by flash evaporating an aqueous solution of hydrogen peroxide (page 5, lines 20-30).

Watling does not appear to disclose that the steps of creating a recirculating heated airstream and progressively introducing hydrogen peroxide/water vapour into the recirculating heated airstream are performed by an apparatus that is disposed within the enclosed space.

O'Neill discloses a method for decontaminating an enclosure comprising creating an airstream within an enclosed space by: (i) drawing air from an atmosphere within the enclosed space to form an air stream, (ii) emitting the airstream back into the atmosphere within the enclosed space; and

Progressively introducing hydrogen peroxide/water vapour into the recirculating airstream (column 2, lines 49-68; column 4, lines 24-55). The reference continues to disclose that the process steps are produced by an apparatus that is substantially handheld and portable while being positioned within the enclosed space in order to allow the apparatus to be readily transported from one enclosed space to another (column 1, lines 45-55). Therefore, it would have been obvious to one of ordinary skill

in the art at the time of the invention to modify the method of Watling to produce the process steps from a portable device that is located inside the enclosure in order to allow the device to be readily transported from one enclosed space to another as exemplified by O'Neill (For more explanation, please see the **Response to Arguments** section of this Office Action). Furthermore, the Manual of Patent Examining Procedures discloses that in *In re Lindberg*, 194 F.2d 732, 93 USPQ 23 (CCPA 1952), a claimed device that is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results (See MPEP 2144.04).

Regarding claims 52 and 63, Watling also discloses that the hydrogen peroxide is removed from the enclosed space after the dew point has been reached and the hydrogen peroxide/water vapour has condensed on the surfaces by circulating the atmosphere containing the hydrogen peroxide/water vapour over a catalyst (page 8, lines 30-37; page 9, lines 1-10). Regarding claims 53 and 55, the reference continues to disclose that the method measures the condensation of the hydrogen peroxide/water vapour on the surfaces by a monitor (page 7, lines 20-27); and terminating the step of introducing hydrogen peroxide/ water vapour into the recirculating heated airstream when the measured condensation has reached a predefined level (page 8, lines 21-30).

Concerning claim 54, Watling also discloses that the method further comprises measuring the condensation in the enclosed space at a number of different locations by condensation monitors to ensure that the condensation has taken place throughout the enclosed space (page 6, lines 25-37; page 7, lines 1-16; page 8, lines 22-30). More

specifically, the method comprises a dew point sensor, a condensation sensor, a gas sensor, a temperature sensor, and a sensor that measures the amount of liquid delivered to the evaporation chamber. Each sensor provided is located at various places throughout the enclosed space and sends an input to a control module (19) that calculates the condensation in the enclosure. Therefore, each sensor is a condensation monitor as broadly defined.

Concerning claims 57 and 58, Watling continues to disclose that the method comprises delivering the heated airstream carrying the hydrogen peroxide/water vapour in a universally rotating jet to distribute the hydrogen peroxide/water vapour throughout the enclosed space (page 6, lines 14-20). Regarding claim 59, the method also discloses using one or more fans within the enclosed space to disperse the hydrogen peroxide/water vapour throughout the enclosed space (page 6, lines 10-13). Regarding claim 66, the reference discloses that the method controls the step of creating a recirculating heated airstream and progressively introducing the hydrogen peroxide/water vapour from outside the enclosed space (page 7, lines 20-37; page 8, lines 1-30).

Regarding claims 69 and 70, Watling is relied upon as set forth in reference to claim 50, wherein the explanations for the limitations of claim 50 are relied upon as necessary. Watling already discloses that the steps of creating a recirculating heated airstream and progressively introducing hydrogen peroxide/water vapour into the recirculating heated airstream are performed by an apparatus comprising a fan (page 3, lines 14-16) for delivering air through a duct (referenced as pipes), a filter (4, 8 and 25)

for filtering air entering the duct, a heater (7) for heating air passing through the duct (page 5, lines 15-20) and a nozzle for delivery of air carrying hydrogen peroxide/ water vapour from the duct, the nozzle being rotated universally to distribute the hydrogen peroxide/water vapour throughout the enclosed space (page 6, lines 10-24), circulation of air carrying the hydrogen peroxide/water vapour through the duct causing decontamination of the duct. More specifically, the hydrogen peroxide circulating through the duct decontaminates the duct as well. Regarding claim 70, the apparatus of Watling comprises the outlet pipe (2) the processing means (3) and the connecting pipe (11) It is noted that the system of Watling was installed by connecting piping to the main enclosed space at some point in time and thus is portable as broadly defined by the claims but is not located inside the enclosed space. However, Watling does not appear to disclose that the device is intended to be portable from one place to another or located inside the enclosed space. O'Neill discloses a method for decontaminating an enclosure comprising creating an airstream within an enclosed space by: (i) drawing air from an atmosphere within the enclosed space to form an air stream, (ii) emitting the airstream back into the atmosphere within the enclosed space; and

Progressively introducing hydrogen peroxide/water vapour into the recirculating airstream (column 2, lines 49-68; column 4, lines 24-55). The reference continues to disclose that device is portable and positioned within the enclosed space in order to allow the device to be readily transported from one enclosed space to another (column 1, lines 45-55). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Watling to make the method more readily

portable in order to allow the device to be readily transported from one enclosed space to another as exemplified by O'Neill (For more explanation, please see the **Response to Arguments** section of this Office Action). Furthermore, the Manual of Patent Examining Procedures discloses that in *In re Lindberg*, 194 F.2d 732, 93 USPQ 23 (CCPA 1952), a claimed device that is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results (See MPEP 2144.04).

Regarding claim 71, the method of Watling also discloses passing the air through a filter (4) as the air is drawn from the atmosphere into the decontamination apparatus (page 5, lines 5-10). Concerning claim 72, the emitted heated airstream is passed out of the apparatus through a rotating nozzle (page 6, lines 13-22). Regarding claim 75, the method discloses that the condensation of the hydrogen peroxide on the surfaces is measured; and that the step of introducing the hydrogen peroxide into the heated airstream when the measured condensation has reached a predefined level is terminated on page 8, lines 20-30. Regarding claim 76, the method also discloses removing the hydrogen peroxide from the enclosed space after the surfaces have been decontaminated (page 9, lines 1-10).

Concerning claim 77, as discussed above O'Neill is relied upon to teach the portability of the apparatus. The method continues to disclose that the apparatus is introduced into a location in order to decontaminate the area, and that the apparatus is portable in order to allow it to be moved from one location to another. Therefore it is known that the apparatus is removed from the enclosed space after the hydrogen

peroxide is removed from the enclosed space and the decontamination procedure is subsequently finished (column 1, lines 34-65). Regarding claim 78, it is also disclosed in the method of O'Neill that the apparatus is positioned within a room, wherein the walls of the room are bounding the enclosed space (column 1, lines 34-65). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Watling to make the method more readily portable in order to allow the device to be readily transported from one enclosed space to another and removed from the enclosed space after the hydrogen peroxide is removed from the space as well as being positioned within the enclosed space that is bounded by walls as exemplified by O'Neill.

Claims 65 and 74 disclose providing a plurality of the decontamination apparatus with the same recirculated airstreams and performing the same method steps as in the previous airstream of introducing hydrogen peroxide vapor into the airstreams. The Manual of Patent Examining Procedures discloses that in *In re Harza*, 274, F.2d 669, 124 USPQ 378 (CCPA 1960), a mere duplication of parts for a multiplied effect has no patentable significance unless a new and unexpected result is produced. Accordingly, the addition of a plurality of portable decontamination apparatus positioned within the enclosed space with a recirculated airstream and introducing hydrogen peroxide vapor into the airstreams is not considered to be patentably distinct from the disclosed method of Watling in view of O'Neill.

4. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watling (WO 00/74734) in view of O'Neill et al (U.S. Patent No. 6,633,105) as applied to claim 55 above, and further in view of Dufresne et al (U.S. Patent No. 6,589,479).

Watling in view of O'Neill is relied upon as set forth above wherein the reference already discloses that the hydrogen peroxide is removed from the enclosed space after the hydrogen peroxide/water vapour has reached the predetermined concentration. Watling does not appear to disclose that biological indicators are used in the enclosed space to determine when the predetermined concentration of hydrogen peroxide/water vapour in the atmosphere has been reached. However, it is conventionally known and commonly used in the art of sterilization to utilize biological indicators for such a purpose. Dufresne discloses an example of this commonly used teaching in a method for monitoring the sterilization of an enclosed space. The method continues to disclose that biological indicators are utilized in order to monitor the sterilization of the enclosed space and notify an operator by a color change on the indicator when the sterilization is complete (column 2, lines 1-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Watling in view of O'Neill to utilize biological indicators in order to monitor the sterilization of the enclosed space and notify an operator by a color change on the indicator when the sterilization is complete, as such is commonly known in the art of sterilization as exemplified by Dufresne.

5. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watling (WO 00/74734) in view of O'Neill et al (U.S. Patent No. 6,6330,105) as applied to claim 51 above, and further in view of Martin (UK Patent Application No. GB 2 360 454 A).

Watling in view of O'Neill is relied upon as set forth above. Watling in view of O'Neill does not appear to disclose that the vapour produced contains 30 to 35% hydrogen peroxide and a balance of water. Martin discloses a method of decontaminating an enclosed space comprising: creating a recirculating heated airstream within an enclosed space by: (i) drawing air from an atmosphere within the enclosed space to form an air stream, (ii) heating the airstream while in the enclosed space, and (iii) emitting the heated airstream back into the atmosphere within the enclosed space: and introducing a sterilant to the airstream until the atmosphere within the space reaches a dew point that causes the sterilant within the atmosphere to condense onto a surface within the space (page 3, lines 1-15). The reference continues to disclose that a 30-35% of hydrogen peroxide solution is utilized because of its sporicidal effects and its fast decontamination (page 1, lines 25-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Watling in view of O'Neill to utilize a 30-35% hydrogen peroxide solution and a balance of water in order to take advantage of its sporicidal and decontaminating effects as exemplified by Martin.

6. Claims 64, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watling (WO 00/74734) in view of O'Neill et al (U.S. Patent No. 6,6330,105) as applied to claim 51 above, and further in view of Childers (U.S. Patent No. 5,173,258).

Watling in view of O'Neill is relied upon as set forth above. Watling does not appear to disclose that the method further comprises removing the hydrogen peroxide by using a heating/ventilation air conditioning system communicating with the enclosed space. Childers discloses a method of decontaminating an enclosed space comprising: creating a recirculating airstream in the enclosed space by (i) continuously drawing air from an atmosphere in the enclosed space, (ii) heating the airstream while in the enclosed space, and (iii) emitting the heated airstream back into the atmosphere in the enclosed space; and progressively introducing hydrogen peroxide vapour into the airstream (column 2, lines 1-30). The method continues to disclose that the hydrogen peroxide is removed from the enclosed space by using a heating/ventilation air conditioning system (column 9, lines 45-60) communicating with the system as disclosed in column 10, lines 5-15. More specifically the unit (10) is a ventilation system for the enclosure (12) that removes the hydrogen peroxide from the enclosure. Regarding claims 67 and 68, the method continues to disclose that the ventilation system (10) is utilized to dehumidify the atmosphere within the enclosed space to reduce the relative humidity thereof to a predetermined level prior to progressively introducing the hydrogen peroxide/water vapour into the recirculating airstream (column 2, lines 3-29). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Watling in view of O'Neill to utilize a ventilation system to remove the hydrogen peroxide from the enclosure and dehumidify the atmosphere within the enclosure in order to convert the sterilant to a suitable nature

and to provide optimal conditions to introduce the hydrogen peroxide into the enclosed space as exemplified by Childers.

Response to Arguments

7. Applicant's arguments filed May 21, 2008 have been fully considered but they are not persuasive.

Applicant's principle arguments are:

(a) It is appreciated that the Watling and the O'Neill methods and systems for decontamination are very different. Watling discloses a fixed system that is mounted outside of a sealed enclosure, while the O'Neill system is specifically designed to function as a portable and manually manipulatable system. That is, it would be impossible to simultaneously and uniformly decontaminate an entire sealed enclosure using the O'Neill system due to the structure and functionality of the wand/nozzle and the UV light that are essential pieces to the system. In contrast, because Watling is saturating the room with a gas so that all surfaces within the room are simultaneously and uniformly decontaminated, Watling does not have any need for portability or manipulation of the system.

As discussed in the previous Office Action, O'Neill is merely relied upon to disclose a portable decontamination system and its advantages of decontaminating enclosures at various locations. For example, one of ordinary skill would look to O'Neill and notice that if the Watling system were made portable, then it would have the obvious advantage of being provided with the ability to decontaminate various enclosures at multiple locations in very simplistic manner. However, it must be noted

that the two references discloses two similar systems, wherein enclosures are decontaminated by utilizing a circulated airstream and introducing hydrogen peroxide to the airstream in order to decontaminate surfaces in the enclosure. It must also be noted that the claims as presented do not limit the method to simultaneous and uniform decontamination of an entire sealed enclosure. Furthermore, The Manual of Patent Examining Procedures discloses that in *In re Lindberg*, 194 F.2d 732, 93 USPQ 23 (CCPA 1952), a claimed device that is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results (See MPEP 2144.04). As such, the claims as set forth are considered to be not patentably distinct from the method of Watling in view of O'Neill.

(b) Furthermore, applicant submits that the Watling system would not function as intended if the preparation region was positioned inside of enclosed space 1. Watling specifically teaches that "because it may be necessary to control the pressure inside the sealed enclosure a pressure control module 21 is used to raise or lower the pressure by supply or extracting air. Thus, pressure within sealed enclosure 1 is controlled by the preparation region drawing in air from the outside surrounding environment through inlet filter 23 or by dispensing gas into the outside surrounding environment through exhaust purification 24. If the preparation region was disposed within sealed enclosure, it would not be able to control the pressure within sealed enclosure 1 by drawing in air from or dispensing gas into the surrounding environment outside of the sealed enclosure. Thus, one skilled in the art would not position the preparation region within sealed enclosure 1 because preparation region would no longer function as intended.

Accordingly, even assuming arguendo that it was obvious to make the preparation region portable so that it could be used with different sealed enclosures as alleged in the Office Action, applicant submits that one skilled in the art would position the preparation region outside of sealed enclosure 1 where it would function as taught and as intended.

The Examiner respectfully draws particular attention to the quotation as listed above by the Applicant, wherein the control of pressure may be necessary. As such, the control of pressure within the enclosure is not a vital step in the method as disclosed by Watling. Furthermore, page 6 lines 30-35 disclose that the pressure control is not essential to the method at hand wherein the disclosure states that the pressure control system may be inactivated when the size of the sealed enclosure is too large or when the pressure control is not required. Therefore, the system of Watling would function as intended within a sealed enclosure, as the control of pressure is not a vital step in the method as set forth.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN C. JOYNER whose telephone number is (571)272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCJ

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797